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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/939,484	08/24/2001	Fabrice Duprat	1201-CIP-DIV-00	3868
35811	7590	02/08/2005	EXAMINER YAEN, CHRISTOPHER H	
IP GROUP OF DLA PIPER RUDNICK GRAY CARY US LLP 1650 MARKET ST SUITE 4900 PHILADELPHIA, PA 19103			ART UNIT 1642	PAPER NUMBER

DATE MAILED: 02/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/939,484

Applicant(s)

DUPRAT ET AL.

Examiner

Christopher H Yaen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Re: Duprat et al
Priority Date: 4 August 1998

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/12/2004 has been entered.
2. Claims 1-8 and 16-23 are canceled without prejudice or disclaimer.
3. Claims 9-15 are pending and examined on the merits.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections Maintained - 35 USC § 101

5. The rejection of claims 9-15 as lacking a specific and substantial asserted well established utility under 35 USC § 101 is maintained for the reasons of record. Applicant rebuts the rejection under 35 USC 101 by addressing three main points raised by the examiner in the paper mailed 4/20/2004 (see page 2 of the response). These points are: (1) what is the TASK protein? (2) how does it function? (3) no specific and substantial asserted well established utility.

With regard to points (1) and (2), applicant points to several pieces of evidence that indicate what the protein is (by indicating the structure and by providing the sequence of the TASK protein (SEQ ID No: 4)) and how the protein functions (by indicating that the instantly claimed protein is an outward rectifying potassium channel). It should be noted that the disclosure provided by the applicant regarding these points are viewed as credible and that the examiner is not specifically questioning the association of the instantly claimed protein as being a potassium channel protein. Thus the assertions that the claimed protein is a potassium channel is credible.

With regard to point (3), applicant contends that the specification sets forth several utilities. More specifically, applicant points to pages 27-29, wherein applicant indicates that methods of screening for drugs that are able to modulate the function of the TASK protein and methods of using those identified drugs for the treatment of disease associated with the TASK protein are some of the asserted utilities. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

The specification has not defined a specific or substantial utility for the claimed TASK protein. The *general* utilities indicated in the specification on pages 27-29 for the claimed TASK protein is applicable to a general class of proteins and therefore the establishment of a specific utility has not been clearly set forth. The methods of drug screening to modulate the function of the TASK protein has not been correlated to a specific modulation of any particular event or for a specific purpose, in other words, what are the reasons for modulating the TASK protein? The specification has not

provided to one of skill in the art at the time of filing any nexus between the specific TASK potassium channel and a method of screening drugs? What types of drugs would be appropriate for one of skill in the art to start such screening point. Essentially, applicant provides a starting point for further experimentation. Applicant sets forth that treatment of disease associated with the TASK protein may be a reason for such modulation, however, the specification nor the art of record has established that the TASK protein is indeed involved in any of the diseases cited or presented in the response (see page 4 of response), and instead only relies on the relation of other potassium channels as evidence that potassium channels are associated with these diseases. Moreover, the TASK protein shares low sequence homology to other channel proteins (TWIK-1 and TREK-1 – see page 23 of specification), wherein the homology is only between 25-28%. The specification also indicates that even in regions of highest homology the sequences only overlap at most ~50% (see page 24). However, reliance on the utility or purported utility of others in the potassium channel class is not sufficient to establish the utility for the instantly claimed TASK channel, because the function of one member in the class of receptors does not translate into the function or utility for the rest of the members of the class.

Thus a "well established utility" is a specific, substantial and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art. Neither a "well-established utility" nor a "specific utility" applies to any utility that one can dream up for an invention or even a utility that would apply to virtually every member of

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a general class of materials, such as proteins or DNA. If this were the case, any product or apparatus, including a perpetual motion machine, would have a well-established utility as landfill or a paper weight; any carbon containing molecule would have a well established utility as a fuel since it can be burned; and any protein would have the above noted "well established" or "specific" utilities. This is not the intention of the statute. In the instant case, the specification provides general, not specific, utilities for the instantly claimed TASK protein, and therefore the asserted utilities although credible are not specific nor substantial and would constitute further experimentation in order to establish a utility. See *Brenner v Manson*, 383 U.S. 519, 535–36, 148 USPQ 689, 696 (1966).

Applicant additionally argues that because the TASK protein is a member of the potassium channel family it would make good targets for drug therapy of diseases associated with potassium channels. Applicant relies on Monsuez J (1997), Yoshino T (1998), Gordon N (1997), and Fujimura N *et al* (1997) to indicate the role of potassium channels in disease such as heart disease and neurodegenerative diseases. Applicant also specifically points to Monsuez J (1997) to indicate that various drugs to potassium channels are effective in treating heart diseases. And concludes that targeting potassium channels would be an excellent target for drug therapies. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record. All of the references relied upon on in the response does not address the specific role of TASK in any of the cited diseases. Although the references provide one of skill in the art with general guidance in terms of the role of potassium

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channels in diseases, it does not provide specific or substantial utility for the instantly claimed TASK protein or any relation to any of the specifically recited diseases.

Finally applicant argues that since the time of filing, others have confirmed the role of TASK in diseases such as those associated with neurons (see page 6 of the response). However, at the time of filing, not specific association of TASK with any disease was known in the prior art or in the specification as originally filed.

Thus the rejection of claims under 35 USC 101 and under 35 USC 112, 1st paragraph as lacking an enabling disclosure due to the lack of a specific or substantially well established utility is maintained for the reasons of record.

Claim Rejections Withdrawn - 35 USC § 102

6. The declarations filed on 11/12/2004 under 37 CFR 1.131 and 37 CFR 1.132 are sufficient to overcome the Leonoudakis *et al* and the Duprat *et al* references.

Conclusion

7. No claim is allowed.

8. This is a continued examination (RCE) of applicant's earlier Application No. 09938484. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen
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January 25, 2005

A handwritten signature in black ink, appearing to read "Gary Nickol", with a stylized flourish at the end.

**GARY NICKOL
PRIMARY EXAMINER**